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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/856,339 | 08/15/2001 | Luet Lok Wong | P02196USO | 7723 |

26271 7590 09/26/2003
FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER

PAK, YONG D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

DATE MAILED: 09/26/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/856,339

Applicant(s)

WONG ET AL.

Examiner

Yong D Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11 & 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on July 18, 2003, amending claims 1-3 and 5, canceling claim4, and adding claims 21-24, has been entered.

Claims 1-3, 5 and 21-24 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on January 17, 2003 and July 18, 2003 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

Art Unit: 1652

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by

Wong et al.

Wong et al. (UK Patent Application GB 2 294 692 A) teach a process for oxidizing acyclic or cyclic monoterpene or a substituted derivative thereof, with a mutant P450_{CAM}, wherein the mutant enzyme comprises of substitution at residue positions 96, 87, 185, 247, and 395, which are located in the active site (pages 4-32). Camphors are monoterpenes. Therefore, the teaching of Wong et al. anticipates claims 1 and 21.

Claims 1 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by

Wong et al.

Wong et al. (UK Patent Application GB 2 306 485 A) teach a process for oxidizing acyclic or cyclic monoterpene or a substituted derivative thereof, with a mutant P450_{CAM}, wherein the mutant enzyme comprises of substitution at residue positions 96, 87, 185, 247, and 395, which are located in the active site (pages 6-31). Camphors are monoterpenes. Therefore, the teaching of Wong et al. anticipates claims 1 and 21.

Claims 1 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by

Wong et al.

Wong et al. (U.S. Patent No. 6,117,661) teach a process for oxidizing acyclic or cyclic monoterpene or a substituted derivative thereof, with a mutant P450_{CAM}, wherein

Art Unit: 1652

the mutant enzyme comprises of substitution at residue positions 96, 87, 185, 247, and 395, which are located in the active site (Columns 3-27). Camphors are monoterpenes. Therefore, the teaching of Wong et al. anticipates claims 1 and 21.

Claims 1 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Flitsch et al.

Flitsch et al. (U.S. Patent No. 6,100,074) teach a process for oxidizing acyclic or cyclic monoterpene or substituted derivative thereof, with a mutant P450_{CAM}, wherein the mutant enzyme comprises of substitution at residue positions 96, 87, 185, 247, and 395, which are located in the active site (Columns 3-28). Camphors are monoterpenes. Therefore, the teaching of Wong et al. anticipates claims 1 and 21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1652

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al.

Wong et al. (UK Patent Application GB 2 294 692 A, UK Patent Application GB 2 306 485 A or U.S. Patent No. 6,117,661) teach a method of oxidizing camphor or derivatives of camphor with a mutant P450 enzyme, as discussed above.

The difference between the reference of Wong et al. and the instant invention is that the reference does not explicitly teach a method of oxidizing various monoterpenes recited in claim 22 nor various sesquiterpenes recited in claims 23-24.

However, Wong et al. teach that the mutant P450 enzyme can oxidize a wide range of organic substrates, including isoprenes or compounds containing isoprene building blocks such as terpenes, monoterpenes, triterpenes, etc. It would have been obvious to one of ordinary skill in the art to apply the method of Wong et al. to various classes of terpenes, such as sesquiterpenes. The monoterpenes recited in claim 22 and sesquiterpenes recited in claim 24 are well known and readily available.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to oxidize monoterpenes and sesquiterpenes recited in claims 22 and 24 with the mutant P450 enzyme of Wong et al. The motivation

Art Unit: 1652

of applying the method of Wong et al. to the various sesquiterpenes and monoterpenes is to efficiently oxidize the said substrates. One of ordinary skill in the art would have had a reasonable expectation of success since Wong et al. successfully oxidized terpenes and teaches that the method can be applied to a wide class of organic compounds.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flitsch et al.

Flitsch et al. (U.S. Patent No. 6,100,074) teach a method of oxidizing camphor or derivatives of camphor with a mutant P450 enzyme, as discussed above.

The difference between the reference of Wong et al. and the instant invention is that the reference does not explicitly teach a method of oxidizing various monoterpenes recited in claim 22 nor various sesquiterpenes recited in claims 23-24.

However, Wong et al. teach that the mutant P450 enzyme can oxidize a wide range of organic substrates, including isoprenes or compounds containing isoprene building blocks such as terpenes, monoterpenes, triterpenes, etc. It would have been obvious to one of ordinary skill in the art to apply the method of Wong et al. to various classes of terpenes, such as sesquiterpenes. The monoterpenes recited in claim 22 and sesquiterpenes recited in claim 24 are well known and readily available.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to oxidize monoterpenes and sesquiterpenes recited in claims 22 and 24 with the mutant P450 enzyme of Wong et al. The motivation

Art Unit: 1652

of applying the method of Wong et al. to the various sesquiterpenes and monoterpenes is to efficiently oxidize the said substrates. One of ordinary skill in the art would have had a reasonable expectation of success since Wong et al. successfully oxidized terpenes and teaches that the method can be applied to a wide class of organic compounds.

Response to Arguments

Applicant's arguments filed on July 18, 2003 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Without the recitation of the SEQ ID NO, it is unclear which residues are at position 96, 87, 185, 247 or 395. The claims have been interpreted using SEQ ID NO:1 as the reference sequence.

Applicants argue that the standard position numbers are used and that there would be no doubt as to the positions of the mutations specified in claim 1. The examiner disagrees. Without a reference sequence identified by a sequence identifier, the position of a specific amino acid residue is unclear. For example, positions of amino

Art Unit: 1652

acids of a polypeptide lacking a Met and a polypeptide having this initial Met residue would occupy different positions.

Claim Rejections - 35 USC § 102

Claims 1-3 and 5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (UK Patent Application GB 2 294 692 A)

Applicants argue that the cited reference does not teach a method of oxidizing monoterpenes excluding (S)-(+)-carvone. The examiner disagrees. Camphors are monoterpenes (pages 14 and 22). Therefore, the teaching of Wong et al. anticipates claims 1-3 and 5.

Claims 1-5 and newly submitted claim 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (UK Patent Application GB 2 306 485 A)

Applicants argue that the cited reference does not teach a method of oxidizing monoterpenes excluding (S)-(+)-carvone. The examiner disagrees. Camphors are monoterpenes (pages 15 and 23). Therefore, the teaching of Wong et al. anticipates claims 1-3 and 5.

Claims 1-5 and newly submitted claim 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (U.S. Patent No. 6,117,661)

Art Unit: 1652

Applicants argue that the cited reference does not teach a method of oxidizing monoterpenes excluding (S)-(+)-carvone. The examiner disagrees. Camphors are monoterpenes (Column 6 and Columns 19-20). Therefore, the teaching of Wong et al. anticipates claims 1-3 and 5.

Claims 1-5 and newly submitted claim 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Flitsch et al. (U.S. Patent No. 6,100,074)

Applicants argue that the cited reference does not teach a method of oxidizing monoterpenes excluding (S)-(+)-carvone. The examiner disagrees. Camphors are monoterpenes (Column 7 and Columns 21-22). Therefore, the teaching of Wong et al. anticipates claims 1-3 and 5.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 1652

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

September 24, 2003



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600